M-END PE- codeine phosphate, phenylephrine hydrochloride, brompheniramine maleate liquid
R.A. McNeil Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

M-END PE

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Brompheniramine Maleate 1.33 mg

Codeine Phosphate 6.33 mg

(WARNING: May be habit-forming)

Phenylephrine Hydrochloride 3.33 mg

Purpose

Antihistamine

Cough Suppressant

Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- nasal congestion
- itching of nose or throat
- runny nose
- itchy, watery eyes
- sneezing
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- chronic pulmonary disease or shortness of breath, or children who are taking other drugs
- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- may cause or aggravate constipation

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not exceed recommended dosage.

Adults and	3 teaspoonfuls every 4 to 6

children 12 years of age and over:	hours, not to exceed 18 teaspoonfuls in a 24 hour period
Children 6 to under 12 years of age:	1 1/2 teaspoonfuls every 4 to 6 hours, not to exceed 9 teaspoonfuls in a 24 hour period
Children under 6 years of age	Not recommended for use

A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

Other information

Store at 59°-86°F (15°-30°C)

Inactive ingredients

citric acid, cotton candy flavor, FD&C Red #40, glycerin, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol

Questions? Comments?

Call 1-423-493-9170

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel and side panel for 354 mL label:

NDC 12830-0754-12

M-END PE

Antihistamine · Antitussive

· Nasal Decongestant

Sugar Free · Alcohol Free

CV

EACH 5 mL (1 TEASPOONFUL)

CONTAINS:

Brompheniramine Maleate .....1.33 mg

Codeine Phosphate.....6.33 mg
(WARNING: May be habit-forming.)

Phenylephrine Hydrochloride.....3.33 mg

Cotton Candy Flavor
12 fl. oz. (354 mL)

Mfg. for:

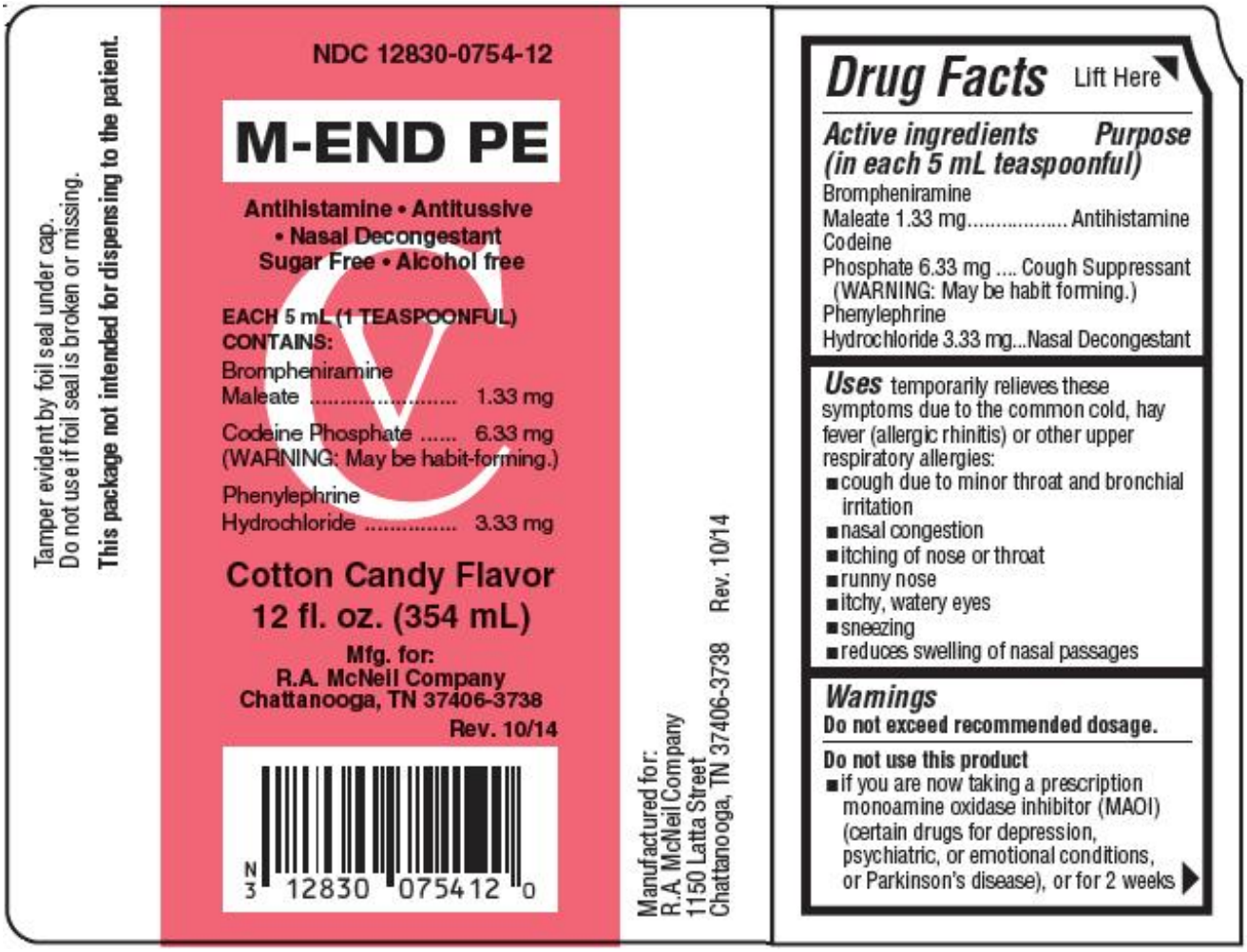
R.A. McNeil Company
Chattanooga, TN 37406-3738

Rev. 10/14

Tamper evident by foil seal under cap.

Do not use if foil seal is broken or missing.

This package not intended for dispensing to the patient.



Drug Facts (continued)

after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

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- heart disease
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- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
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Drug Facts (continued)

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M-END PE

codeine phosphate, phenylephrine hydrochloride, brompheniramine maleate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12830-754
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	6.33 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	3.33 mg in 5 mL
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1.33 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	COTTON CANDY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12830-754-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/19/2014	
2	NDC:12830-754-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/11/2008	

Labeler - R.A. McNeil Company (008305220)

Registrant - Woodfield Pharmaceutical, LLC (079398730)

Establishment

Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceutical, LLC		079398730	manufacture(12830-754)

Revised: 11/2021 R.A. McNeil Company